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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,949	06/26/2001	Cindy A. Sprecher	00-42	4092

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,949	SPRECHER ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-17,24 and 33-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-17,24 and 33-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/04/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

1a. Receipt of Applicants' amendments and arguments filed 26 February 2004 is acknowledged. Claims 1, 2, 6, 9, 12 and 14 have been amended. Claims 3, 4, 18-23 and 25-32 have been cancelled and new claims 33-44 have been added. Thus claims 1, 2, 5-17, 24 and 33-44 are under consideration.

1b. Receipt of Applicants' declarations under 37 C.F.R §1.132, filed on 26 February 2004 by Dr. Janine Bilsborough is also acknowledged.

Information Disclosure:

1c. Applicants are thanked for providing copies of the references cited on the on the PTO-1449 form submitted by Applicants on 03 June 2003.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 02/26/04:

(I) The objection to the specification for not containing a title that is descriptive of the invention is withdrawn.

(II) The objection to the Brief Description of the Drawings for not describing Figure 1A , Figure 1B and Figure 1C, is withdrawn.

(III) The objection to claims 1-17 and 24 for reciting non-elected SEQ ID Nos, is withdrawn.

Response to Applicants' arguments:

3. Applicants' arguments have been fully considered and are persuasive in part. The remaining issues are as follows.

Claim Rejections under 35 U.S.C. §101/112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4a. Claims 1, 2, 5-17, 24 stand rejected and new claims 33-44 are also rejected under U.S.C. §101 for reasons of record set forth in the office action mailed on 26 August 2003, pages 4-7, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants cite Dr. Bilsborough's Declaration, which will be addressed in paragraph 5a (below) of the office action. Applicants argue that after reading the instant application one of skill in the art would immediately appreciate the usefulness of the claimed invention, because the specification discloses that the claimed invention plays a role in inducing inflammation by immune response cells. Applicants content that since zcytor17 expression is up-regulated in monocytes, activated CD4+ and CSD8+ T cells, therefore, zcytor17 expression is up-regulated during an immune-mediated inflammatory response. Applicants further argue that U.S Serial No. 10/351,157 filed on 21 January 2003, which was considered by the Examiner, discloses that the cognate ligand for zcytor17 promotes cellular proliferation, which was diminished by a soluble form of the zcytro17. Applicants Further contend zytcor17 is up-regulated in the involved samples from patients diagnosed with inflammatory bowel disease (IBD) and psoriaias. Finally, Applicants argue that the Examiner has provided no evidence or scientific basis to refute the assertion of the utility for the polypeptides of the present invention.

These arguments have been fully considered, but are notfound persuasive. With respect to Applicants' first argument, the fact that the polypeptides of the instant invention are up-regulated on monocytes, activated CD4+ and CD8+ T cells, does not provide the claimed invention with either a specific and substantial asserted utility or a well established utility, because there is no information regarding how and what is the specific role that said polypeptide play in inflammation. The role of the claimed nucleic acids or the encoded polypeptides in inflammation is not disclosed by Applicants. With respect to Applicants' second and third arguments the data from the post-filing date application 10/351,157 can not be used to establish either a specific and substantial asserted utility or a well established utility for the polypeptide of the instant invention, because the current application must satisfy the requirements under U.S.C. §101 at the time of filing of the instant application. Furthermore, the instant specification does not disclose that the expression of the zcytor17 polypeptides are up-regulated in tissue samples of IBD patients. Thus the zcyto-17 cannot be used to diagnose inflammatory bowel disease, because its involvement in IBD is not disclosed in the current application. Finally, contrary to Applicants' contention, the Examiner has provided sound scientific reasoning as to why the claimed invention lacks a specific and substantial asserted utility and a well established utility, because the physiological significance of the claimed nucleic acids or the encoded polypeptides have not been established as of the time of the filing of the instant application.

Claim Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4b. Claims 1, 2, 5-17, 24 stand rejected and new claims 33-44 are also rejected under U.S.C. §112, first paragraph for reasons of record set forth in the office action mailed on 26 August 2003, pages 7-8.

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants contend that the claimed invention is supported by a specific utility that is substantial and credible. Applicants further contend that upon reading the instant specification one of skill in the art would know how to make and use the proteins of the present invention.

This is not found persuasive, because as set forth directly above, instant specification does not establish the role of the claimed nucleic acids or the encoded polypeptides in inflammation. The disclosure that the polypeptides of the instant invention are up-regulated in monocytes, activated CD4+ and CSD8+ T cells, is not sufficient to establish a readily available utility for the claimed inventions, because there is no information regarding as to how said polypeptides ire involved in inflammation, as a result one of skill in the art would not know how to use them. The fact that the polypeptides of the instant invention are up-regulated in monocytes, activated CD4+ and CSD8+ T cells only

establishes that said polypeptides ***might*** play a role in immune response. However, further research is required to establish whether the polypeptides of the instant invention actually play a role in immune response and if so how. Thus, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility.

Finally, the amount of experimentation required for one of ordinary skill in the art to make and use the claimed invention, an isolated nucleic acid encoding the polypeptide that comprise fragments 20-227, 20-519, 20-542, 544-732 or 520-543 of SEQ ID NO: 2, that displays that desired activity, would be undue. Applicants do not teach which regions of the polypeptide of SEQ ID NO:2, are critical for the functional and structural integrity of the polypeptide. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid, which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation.

37 CFR 1.132 Declaration:

5. The declarations under 37 C.F.R §1.132, filed on 26 February 2004 by Dr. Janine Bilsborough is insufficient to overcome the rejection of 1, 2, 5-17, 24 and 33-44 made under 35 U.S.C. 101/112.

Dr. Bilsborough submits that the instant specification discloses that the zcytor17 polypeptides play a role in inducing inflammation by immune response cells, e.g, monocytes and T cells upon binding zcytor17 ligand. Dr. Bilsborough contends that the cell types and growth conditions that affect zcytor17 expression is useful means of elucidating its function and predicting a source of ligand. Dr. Bilsborough submits that zcytor17 expression is strongly stimulated by hIFNγ, a well-known pro-inflammatory cytokine. Dr. Bilsborough also submits that zcytor17 is expressed on activated CD4+ and CD8+ T cells. Dr. Bilsborough argues that U.S Application No. 10/351,157 discloses that a cognate ligand for zcytor17 promotes cellular proliferation, which was diminished by a soluble form of the zcytro17. Dr. Bilsborough also contends that zytcor17 polypeptides are up-regulated in the involved samples from patients diagnosed with inflammatory bowel disease (IBD) and psoriasis. Finally, Dr. Bilsborough concludes that zcytor17 polypeptides of the instant application are able to induce inflammation by proliferating immune response cells and that these polypeptides exhibit a physiologically significant real-world use.

These arguments have been fully considered but are not deemed persuasive. Firstly, identifying the cell types and growth conditions that affect zcytor17 in order to elucidate its function and its cognate ligand, does not afford a readily available utility for the polypeptides of the instant invention, because

further research is required to identify the function and physiological relevance of these polypeptides. The instant specification does not disclose the cognate ligand for the polypeptides of the instant invention. Secondly, the fact that hIFNγ induces the expression of zcytor17 on monocytes and that zcytor17 is expressed on activated CD4+ and CD8+ T cells only establishes that said polypeptides ***might*** play a role in immune response, however, further research is needed to elucidate if and how said polypeptides are involved in inflammation. Thirdly, the data from the post-filing date application 10/351,157 cannot be used to establish either a specific and substantial asserted utility or a well established utility for the polypeptide of the instant invention, because the current application must satisfy the requirements under U.S.C. §101 at the time of filing of the instant application. Finally, the instant specification does not disclose that the expression of the zcytor17 polypeptide is up-regulated in tissue samples of IBD patients. Therefore, the zcyto-17 polypeptides cannot be used to diagnose inflammatory bowel disease, because their involvement in IBD is not disclosed in the current application. There is no doubt that the polypeptides of the instant invention are physiologically significant, however, further research is required to identify the cognate ligand for these polypeptides and to elucidate the specific role that they play in immune response. Thus, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility.

New Rejections and Issues:

Priority:

6a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is not supported by the disclosure in application serial no. 60/214,282, filed on 26 June 2000, because, although the polypeptide of SEQ ID NO:2(zcyto-17) and the nucleic acid encoding said polypeptide, are disclosed in application 60/214,282, none of the parent applications provide a specific and substantial asserted utility or a well established utility for the claimed invention. Accordingly, the subject matter defined in claims 1, 2, 5-17, 24, 33-44, is afforded an effective filing date 26 June 2001, which is the filing date of the current application.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 06/26/2001, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 06/26/2001.

Claim Rejections under 35 U.S.C. §102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7a. Claims 1, 2, 5, 9 and 13 are rejected under U.S.C. § 102 (a) as being anticipated by Maeda et al (WO 00/75314; published 14 December 2000).

Maeda et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:2 of the instant application, from amino acid residue 20 to amino acid residue 227. (See attached copies of the comparison of SEQ ID NO:2 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Maeda et al also disclose the nucleic acid encoding said polypeptide, an expression vector comprising said nucleic acid and a host cell expressing the encoded polypeptide. Instant claims 1, 2, 5, 9 and 13 are drawn to an isolated nucleic acid encoding the polypeptide comprising the amino acid sequence as shown in SEQ ID NO:2, from amino acid number 20 (Ala) to amino acid number 227 (Pro), an expression vector comprising said nucleic acid and a host cell comprising said expression vector.

Therefore, the Maeda et al reference anticipates instant claims 1, 2, 5, 9 and 13 in the absence of any evidence to the contrary.

Claim Rejections under 35 U.S.C. §103:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 9, 10, 14-17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maeda et al in view of Capon et al., U.S. Patent Number 5,116,964.

The teachings of Maeda et al. are discussed above. Maeda et al. do not teach fusion protein comprising the proteins of Maeda's invention.

Capon teaches fusion proteins comprising immunoglobulin polypeptides fused to "ligand binding partners", which are defined as including hormones and growth factors (see column 2, lines 14-19). At column 4, lines 38-43, Capon states that the immunoglobulin (Ig) fusions of the invention "serve to prolong the in vivo plasma half-life of the ligand binding partner..." and "facilitate its purification by protein A". Also taught are recombinant materials for making such a fusion protein, vectors and expression; see columns 15-16. Preferred embodiments include sequences including the hinge regions of IgG-1, -2, -3 or -4, IgA, IgE, IgD and IgM, see column 14, lines 40-45 (the first domain of the constant region can be omitted). The preferred species of Ig was human, see claims 8-9. Capon states that the DNA sequences for the Ig chains were well known in the art at the time the invention was made, see column 15 beginning at line 40.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the proteins of Maeda et al. to make fusion proteins as taught by Capon et al. The person of ordinary skill in the art would have been motivated to make the modification in view of Capon's disclosure that fusion proteins facilitate purification of desired proteins. Accordingly, the invention, taken as a whole, is prima facie obvious over the cited prior art.

Conclusion:

9. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud

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31 may 2004

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